



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2004

Ms. Carol Ruggiero
Director of Regulatory Affairs
Cliniqa Corporation
1432 South Mission Road
Fallbrook, CA 92028

Re: k041898
Trade/Device Name: CLINIQA Liquid QC™ TDM Controls Levels 1,2&3
CLINIQA LiniCAL™ TDM Calibration Verifiers Levels A- E for
Olympus AU
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: July 12, 2004
Received: July 14, 2004

Dear Ms. Ruggiero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

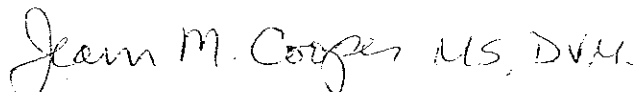
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in dark ink, reading "Jean M. Cooper MS, D.V.M.", written in a cursive style.

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K041898

Device Name: CLINIQA Liquid QC™ TDM Controls Levels 1, 2 & 3

Indications For Use:

CLINIQA Liquid QC™ TDM Controls Levels 1, 2 & 3 are intended for use as an assayed quality control material. Three assayed levels of Acetaminophen, Amikacin, Carbamazepine, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid and Vancomycin are provided.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041898

510(k) Number (if known): K041898

Device Name: CLINIQA LiniCAL™ TDM Calibration Verifiers Levels A – E for Olympus AU Systems™.

Indications For Use:

CLINIQA LiniCAL™ TDM Calibration Verifiers Levels A – E for Olympus AU Systems™ are assayed, liquid, quality control products which may be used to evaluate the performance of the Olympus AU Systems™ for Acetaminophen, Amikacin, Caffeine, Carbamazepine, Digoxin, Disopyramide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Theophylline, Tobramycin, Valproic Acid and Vancomycin at five useful concentrations

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


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Device Evaluation and Safety

510(k) K041898